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10/635,003	08/06/2003	Victor Zurita	32722-2002	7483
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TORYS LLP			FIELDS, COURTNEY D	
79 WELLINGTON ST. WEST				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/635,003	<b>Applicant(s)</b> ZURITA ET AL.
	<b>Examiner</b> COURTNEY D. FIELDS	<b>Art Unit</b> 2137

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 08 February 2008.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-23 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

1. Claims 1-23 are pending.

***Response to Arguments***

2. Applicant's arguments with respect to claims 1-2, 12, and 23 have been considered but are moot in view of the new ground(s) of rejection, Williams et al. (US Patent No. 6,691,070).

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-2, 11-12, and 21-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Williams et al. (US Patent No. 6,691,070).

Referring to the rejection of claim 1, Williams et al. discloses a computer-implemented method of validating a computer system comprising the steps of:

- (i) receiving data representative of a plurality of requirements for validating said computer system (See Column 2, lines 54-67)
- (ii) generating a validation plan to validate the computer system based on said received data (See Column 5, lines 63-67, Column 6, lines 1-17)
- (iii) determining a computing environment appropriate to said computer system based on said received data (See Column 6, lines 18-32)

(iv) generating a plurality of tests for the computer system to be performed during an implementation of said validation plan (See Column 10, lines 23-30)

(v) presenting said tests to a user as part of said implementation (See Column 10, lines 30-42)

(vi) receiving responses from said user as to a status of said tests (See Column 11, lines 14-19)

(vii) generating a validation report based on said responses (See Column 13, lines 23-29)

(viii) presenting a non-validation message if said validation report indicates said system failed one or more of said tests (See Column 12, lines 55-64)

(ix) presenting a validation message if said validation report indicates said system meets said tests (See Column 12, lines 35-54)

and, (x) repeating one or more of the foregoing steps until said validation report indicates said system meets said tests (See Column 2, lines 54-67)

Referring to the rejection of claims 2, 12 and 22, Williams et al. discloses a computer-implemented method, apparatus, and readable media of validating a computer system comprising the steps of:

receiving a plurality of validation requirements for said computer system (See Column 2, lines 54-67)

receiving data representative of the results of performing each validation requirement, said results including whether the computer system achieved a particular

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requirement was achieved and exception reports for each requirement that was not achieved (See Column 16, lines 4-16)

and, generating a report for each of said requirements, said report including a message indicating whether said system is validated if a defined set of said requirements are achieved (See Column 13, lines 23-29)

Referring to the rejection of claims 11 and 21, Williams et al. discloses the claimed limitation wherein comprising the additional step of presenting a report summarizing each of said requirements (See Column 16, lines 4-16)

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3-10, 13-20, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US Patent No. 6,691,070) in view of Brinkman et al. (Pub No. 2005/0065818).

Williams et al. discloses the claimed limitation as disclosed. However, Williams et al. fails to explicitly disclose third-party qualifications, audits, and computer-based training sessions for the users. Brinkman et al. discloses a computer implemented and/or assisted health information system for tracking and/or ensuring appropriated patient care, whereby the system facilitates client access to health professionals for an enrolled population.

Referring to the rejection of claims 3 and 13, (Williams et al. modified by Brinkman et al.) discloses the claimed limitation wherein said computer system is a computer system used in the pharmaceutical industry (See Brinkman et al., page 4, Section 0059)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Williams et al.'s system for monitoring a controlled environment for validating a computer system with Brinkman et al.'s computer integrated medical system. Motivation for such an implementation would enable a method and/or system to provide a single, integrated means for tracking and/or monitoring client member usage for health, pharmaceutical, and management services. (See Brinkman et al., page 2, Section 0023)

Referring to the rejection of claims 4 and 14, (Williams et al. modified by Brinkman et al.) discloses the claimed limitation wherein said computer system is a computer system used in the health care industry (See Brinkman et al., page 4, Section 0068)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Williams et al.'s system for monitoring a controlled environment for validating a computer system with Brinkman et al.'s computer integrated medical system. Motivation for such an implementation would enable a method and/or system to provide a single, integrated means for tracking and/or monitoring client member usage for health, pharmaceutical, and management services. (See Brinkman et al., page 2, Section 0023)

Referring to the rejection of claims 5 and 15, (Williams et al. modified by Brinkman et al.) discloses the claimed limitation wherein said validation requirements include at least one of a installation qualification, operational qualification, performance qualification, a third-party qualification (See Brinkman et al., page 5, Section 0071)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Williams et al.'s system for monitoring a controlled environment for validating a computer system with Brinkman et al.'s computer integrated medical system. Motivation for such an implementation would enable a method and/or system to provide a single, integrated means for tracking and/or monitoring client member usage for health, pharmaceutical, and management services. (See Brinkman et al., page 2, Section 0023)

Referring to the rejection of claims 6 and 16, (Williams et al. modified by Brinkman et al.) discloses the claimed limitation wherein said third-party qualification is based on 21 CFR Part 11 (See Brinkman et al., page 9, Section 0097)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Williams et al.'s system for monitoring a controlled environment for validating a computer system with Brinkman et al.'s computer integrated medical system. Motivation for such an implementation would enable a method and/or system to provide a single, integrated means for tracking and/or monitoring client member usage for health, pharmaceutical, and management services. (See Brinkman et al., page 2, Section 0023)

Referring to the rejection of claims 7 and 17, (Williams et al. modified by Brinkman et al.) discloses the claimed limitation wherein said installation qualification, said operational qualification, said performance qualification, and said third-party qualification each include at least one of a hardware requirement, a user requirement, a test objective, and a test instruction (See Brinkman et al., page 4, Section 0064)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Williams et al.'s system for monitoring a controlled environment for validating a computer system with Brinkman et al.'s computer integrated medical system. Motivation for such an implementation would enable a method and/or system to provide a single, integrated means for tracking and/or monitoring client member usage for health, pharmaceutical, and management services. (See Brinkman et al., page 2, Section 0023)

Referring to the rejection of claims 8 and 18, (Williams et al. modified by Brinkman et al.) discloses the claimed limitation wherein said validation requirement further includes an audit respective to said installation qualification, said operational qualification, said performance qualification, and said third-party qualification (See Brinkman et al., page 7, Section 0086)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Williams et al.'s system for monitoring a controlled environment for validating a computer system with Brinkman et al.'s computer integrated medical system. Motivation for such an implementation would enable a method and/or system to provide a single, integrated means for tracking

and/or monitoring client member usage for health, pharmaceutical, and management services. (See Brinkman et al., page 2, Section 0023)

Referring to the rejection of claims 9 and 19, (Williams et al. modified by Brinkman et al.) discloses the claimed limitation wherein said audit is comprised of predefined checklist reflecting best practices applicable to an identifiable type of said system (See Brinkman et al., page 7, Section 0086)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Williams et al.'s system for monitoring a controlled environment for validating a computer system with Brinkman et al.'s computer integrated medical system. Motivation for such an implementation would enable a method and/or system to provide a single, integrated means for tracking and/or monitoring client member usage for health, pharmaceutical, and management services. (See Brinkman et al., page 2, Section 0023)

Referring to the rejection of claims 10 and 20, (Williams et al. modified by Brinkman et al.) discloses the claimed limitation wherein said report indicates that said requirements are not achieved unless an affirmative response that each requirement was achieved has been received (See Brinkman et al., page 7, Section 0085)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Williams et al.'s system for monitoring a controlled environment for validating a computer system with Brinkman et al.'s computer integrated medical system. Motivation for such an implementation would enable a method and/or system to provide a single, integrated means for tracking

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and/or monitoring client member usage for health, pharmaceutical, and management services. (See Brinkman et al., page 2, Section 0023)

Referring to the rejection of claim 23, (Williams et al. modified by Brinkman et al.) discloses a method of restricting access to a computing apparatus comprising the steps of:

delivering a computer-based training session to a user, said session for instructing said user how to operate said apparatus (See Brinkman et al., page 7, Section 0089)

generating a unique user code respective to said user provided said user successfully completes said training session (See Brinkman et al., page 7, Section 0089)

presenting a user-login dialogue on said apparatus, said dialogue requesting an identification of said user and said user code (See Brinkman et al., page 8, Section 0090)

allowing access to said computing apparatus if a received identification and a received user code match said user and said user code and otherwise refusing access to said computing apparatus (See Brinkman et al., page 8, Section 0091)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Williams et al.'s system for monitoring a controlled environment for validating a computer system with Brinkman et al.'s computer integrated medical system. Motivation for such an implementation would enable a method and/or system to provide a single, integrated means for tracking

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and/or monitoring client member usage for health, pharmaceutical, and management services. (See Brinkman et al., page 2, Section 0023)

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Courtney D. Fields whose telephone number is 571-272-3871. The examiner can normally be reached on Mon - Thurs. 6:00 - 4:00 pm; off every Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Emmanuel Moise can be reached on 571-272-3865. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Courtney D. Fields/  
Examiner, Art Unit 2137  
May 8, 2008

/Emmanuel L. Moise/

Supervisory Patent Examiner, Art Unit 2137